DARZALEX® SC daratumumab subcutaneous

DARZALEX® daratumumab concentrate for solution for infusion

DARZALEX® – OPEN A NEW DIMENSION OF COMBINATION EFFICACY

Newly diagnosed multiple myeloma

Frontline DARZALEX® + VTd for TE patients*[1]

39%

HR=0.61; 95% CI, 0.52–0.72; p<0.0001

Reduction in risk of disease progression or death (vs VTd)

mPFS 83.7 mo

Frontline DARZALEX® + Rd for TIE patients†[2]

45%

HR=0.55; 95% CI, 0.45–0.67; p<0.0001

Reduction in risk of disease progression or death (vs Rd)

mPFS 61.9 mo

Frontline DARZALEX® + VRd[3–5]

For TE patients‡[3]

58%

HR=0.42; 95% CI, 0.30–0.59; p<0.001

For TIE patients§[4]

43%

HR=0.57; 95% CI, 0.41–0.79; p=0.0005

Reduction in risk of disease progression or death (vs VRd)[3,4]

Estimated 84.3% PFS rate at 4.0 yrs (95% CI, 79.5–88.1)|[3,5]

Estimated 68.1% PFS rate at 4.5 yrs (95% CI, 60.8–74.3)|[4,5]

Relapsed/refractory multiple myeloma

DARZALEX® + Rd for patients ≥1 PLOT¶[6]

56%

HR=0.44; 95% CI, 0.35–0.54; p<0.0001 (vs Rd)

DARZALEX® + Vd for patients with 1 PLOT#[7]

78%

HR=0.22; 95% CI, 0.15–0.32; p<0.0001 (vs Vd)

Reduction in risk of disease progression or death

mPFS 45.0 mo **mPFS 27.0 mo**

DARZALEX® + Pd for patients ≥1 PLOT containing a PI and lenalidomide and were lenalidomide-refractory**[8]

37%

HR=0.63; 95% CI, 0.47–0.85; two-sided p=0.0018

Reduction in risk of disease progression or death (vs Pd)

mPFS 12.4 mo

*CASSIOPEIA is a multicentre, randomised, open-label, phase III trial evaluating the safety and efficacy of DARZALEX® + VTd vs VTd in TE NDMM patients. Patients (N=1,085) were randomised 1:1 to receive either DARZALEX® + VTd or VTd alone.[1]
†MAIA is a multicentre, randomised, open-label, phase III trial evaluating the safety and efficacy of DARZALEX® + Rd vs Rd in TIE NDMM patients. Patients (N=737) were randomised 1:1 to receive either DARZALEX® + Rd or Rd alone.[2]
‡PERSEUS is a multicentre, randomised, phase III trial evaluating DARZALEX® + VRd vs VRd in TE NDMM patients. Patients (N=709) were randomised 1:1 to receive DARZALEX® + VRd before and after transplantation, followed by lenalidomide maintenance therapy, or VRd alone before and after transplantation, followed by lenalidomide maintenance therapy.[3]
§CEPHEUS is a randomised phase III trial evaluating DARZALEX® + VRd vs VRd in patients with NDMM who were TIE or for whom transplant was not planned as the initial therapy (transplant deferred). Patients (N=395) were randomised 1:1 to receive eight cycles of DARZALEX® + VRd or VRd followed by DARZALEX® + Rd or Rd until progression.[4]
|mPFS not reached for DARZALEX® + VRd.[5]
¶POLLUX was a multicentre, randomised, open-label, phase III trial in RRMM patients with ≥1 PLOT. Patients (N=569) were randomised 1:1 to receive either DARZALEX® + Rd or Rd alone.[6]
#CASTOR was a multicentre, randomised, open-label, phase III trial in RRMM patients with ≥1 PLOT. Patients (N=498) were randomised 1:1 to receive DARZALEX® + Vd or Vd alone. Data presented is for the subgroup of patients with 1 PLOT.[7]
**APOLLO is a multicentre, randomised, open-label, phase III trial evaluating the safety and efficacy of DARZALEX® + Pd vs Pd in patients with RRMM who received ≥1 PLOT containing a PI and lenalidomide, had a partial response or better to one or more previous lines of anti-myeloma therapy and were refractory to lenalidomide if only one previous line of therapy was received. Patients (N=304) were randomised 1:1 to receive either DARZALEX® + Pd or Pd alone.[8]

Abbreviations: CI, confidence interval; HR, hazard ratio; mo, months; mPFS, median progression-free survival; NDMM, newly diagnosed multiple myeloma; Pd, pomalidomide+dexamethasone; PFS, progression-free survival; PI, proteasome inhibitor; PLOT, prior line of treatment; Rd, lenalidomide+dexamethasone; RRMM, relapsed/refractory multiple myeloma; TE, transplant-eligible; TIE, transplant-ineligible; Vd, bortezomib+dexamethasone; VRd, bortezomib+lenalidomide+dexamethasone; vs, versus; VTd, bortezomib+thalidomide+dexamethasone; yrs, years.

References: 1. Moreau P, et al. *Lancet Oncol.* 2024;25(8):1003–14. **2.** Facon T, et al. *Leukemia.* 2025;39(4):942–50. **3.** Sonneveld P, et al. *N Engl J Med.* 2024;390(4):301–13. **4.** Usmani SZ, et al. *Nat Med.* 2025;31(4):1195–202. Erratum in: *Nat Med.* 2025;31(4):1366. **5.** Sonneveld P. Presented at the 6th European Myeloma Network (EMN) meeting, 10–12 April 2025; Athens, Greece. **6.** Dimopoulos MA, et al. *J Clin Oncol.* 2023;41(8):1590–99. **7.** Mateos MV, et al. *Clin Lymphoma Myeloma Leuk.* 2020;20(8):509–18. **8.** Dimopoulos MA, et al. *Lancet Oncol.* 2021;22(6):801–12.

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Scan to read **DARZALEX® SC** Abbreviated Prescribing Information

Scan to read **DARZALEX® IV** Abbreviated Prescribing Information